Feng, Shixia

From: Feng, Shixia
Sent: Tuesday, February 04, 2003 4:41 PM
To: 'Nathalie.Rousselle@mdsps.com'; robin.kinser@pmusa.com; Feng, Shixia
Cc: Chad.Briscoe@mdsps.com; Kirk.Newland@mdsps.com; Troy.Bradley@mdsps.com; Jacques.Prevost@mdsps.com
Subject: RE: Method transfer procedure

That's fine. We will review these documents on-site. Thanks for the information.

Best regards,
Shixia

-----Original Message-----
From: Nathalie.Rousselle@mdsps.com [mailto:Nathalie.Rousselle@mdsps.com]
Sent: Tuesday, February 04, 2003 4:23 PM
To: robin.kinser@pmusa.com; shixia.feng@pmusa.com
Cc: Chad.Briscoe@mdsps.com; Kirk.Newland@mdsps.com; Troy.Bradley@mdsps.com; Jacques.Prevost@mdsps.com
Subject: Method transfer procedure

Dear Ms. Kinser and M. Feng

With regards to your request for the method transfer procedure, please be assured that although this document is in place, we cannot provide a copy for review before your visit. This document is a controlled document and MDS PS policy is not to provide copies of controlled documents for distribution outside MDS PS.

However, the pertinent documents, the SOP on "Chromatographic and Spectrometric Methods: Validation" (GL-BI-10601-00) and the working instructions WI-ALG-02-00 "Between-Site Partial Validation" (which goes into more detail) will be available for your review when you will visit our facility on February 10th and 11th. In summary, a minimum of three batches to determine the inter-batch precision and accuracy are required to cross-validate a method between different sites of MDS PS.

If this does not accommodate your needs, do not hesitate to contact us.

Thank you,

Nathalie Rousselle
Associate Director Operations- Bioanalysis
514-333-0042 ext 4193

validation to production transition